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DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE

Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
TELEPHONE: 303-236-3000
FACSIMILE: 303-236-3551

June 19, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Andrew J. Tofe, Ph.D.
President/CEO
CeraMed Dental, L.L.C.
12860 West Cedar Drive, Suite #100
Lakewood, CO 80232

PURGED

Ref. # DEN-97-20

Dear Dr. Tofe:

During an inspection of CeraMed Dental L.L.C. conducted between March 25 and April 2, 1997, Investigator Lynnette I. Riggio and Microbiologist Steven C. Madzo determined that your firm manufactures various sterile endosseous implants. These products are medical devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacturing, packing, storage, or installation are not in conformance with Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations, Part 820 (21 CFR 820) as follows:

1. Failure to conduct all processing control operations in a manner designed to assure that the device conforms to applicable specifications, as required by 21 CFR 820.100(b)(2). For example, sterility validation performed for ethylene oxide sterilization of PermaRidge products was not conducted on the normal sterilization load configuration.

2. Failure to establish adequate procedures for specification control measures to assure the design basis for the device and components is correctly translated into approved specifications, as required by 21 CFR 820.100(a)(1). For example, your firm does not have adequate procedures to assure that validation protocols are prepared and adhered to in the conduct of the validation study.

3. Failure to conduct planned and periodic audits of the quality assurance program, as required by 21 CFR 820.20(b). For example, internal quality assurance audits have not been conducted in the areas of [redacted]. Your firm [redacted] procedure ([redacted]) requires annual audits of all operations.

4. Failure to provide all personnel with the necessary training to perform their assigned responsibilities adequately, as required by 21 CFR 820.25(a). For example, no training program has been developed to train personnel performing manufacturing operations requiring aseptic technique for the PermaRidge product line. Further, there is no documentation to demonstrate that the clean room supervisor, who is responsible for training all clean room employees, has the necessary education, background, training or experience to assure that all operations are correctly performed, as required by 21 CFR 820.25.

5. Failure to control environmental conditions to prevent contamination of the device, as required by 21 CFR 820.46. For example, poor practices are employed in disinfecting the class 100 laminar flow hood, there is no continuous monitoring of air pressure differentials in either the class 10,000 or class 100,000 clean rooms, and no environmental monitoring is performed in the class 100 laminar flow hood during aseptic operations.

6. Failure to maintain a device history record to demonstrate that the device is manufactured in accordance with the device master record, as required by 21 CFR 820.184. For example, device history records do not reflect the actual manufacturing process or components used in the manufacture of PermaRidge.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

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We have completed review of your responses dated April 10, 1997, and May 5, 1997. In your April 10, 1997, response to observation #7 on the FDA 483, you state that the environmental monitoring already required and performed quarterly has consistently documented the effectiveness of your cleaning procedure. However, there is no indication in your environmental monitoring reports as to when such monitoring is performed, whether just after cleaning or at some later time. If your monitoring is being performed just after cleaning then the presence of microbial isolates indicates that your cleaning procedures are not effective.

Your April 10, 1997, response to observation #10 on the FDA 483 states that your firm does not have any specific requirement or qualifications for employment regarding education, background, or work history. As stated previously in this letter, the Good Manufacturing Practice (GMP) Regulation requires each manufacturer to have sufficient personnel with the necessary education, background, training, and experience to assure that all operations are correctly performed under 21 CFR 820.25. Your firm has failed to fulfill this requirement.

The remainder of your responses appear to be adequate and will be fully evaluated during our next inspection.

Federal agencies are advised of the issuance of all Warning Letters regarding medical devices so they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for class III devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

Please notify this office within 15 days of receipt of this letter, of the specific steps you will be taking to comply with our request.

Your reply should be sent to the Food and Drug Administration, Denver District Office, Attention: David K. Glasgow, Acting Compliance Officer, at the above address.

Sincerely,

Gary C. Dean

Gary C. Dean
District Director

PURSUANT